K010042

JAN 3 0 2001

GE Medical Systems
General Electric Company
P O Box 414 Milwaukee, WI 53201

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Submitter Larry A. Kroger, Ph.D.
Senior Regulatory Program Manager
Telephone: (414) 544-3894, FAX: (262) 544-3863
Date Prepared: November 30th, 2000

PRODUCT IDENTIFICATION

Name: CT Perfusion 2

Classification Name: Accessory to Computed Tomography System

Manufacturer : General Electric Medical Systems
283, rue de la Miniere
78533 Buc Cedex, FRANCE

Distributor: General Electric Medical Systems, Milwaukee, WI

Marketed Devices The CT Perfusion 2 is substantially equivalent to the device listed below:

Model:	CT Perfusion
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K993791

Device Description:
CT Perfusion 2 is an enhanced version of CT Perfusion, an image analysis and visualization software product. It allows the user to produce dynamic image data and generate functional information regarding perfusion and related parameters from measuring changes in image intensity over time. The software runs on Advantage Windows (AW) platform, displaying the analysis data in a user-friendly graphic format and as parametric* images.

Note: A parametric image is single image that is calculated from a set of time course images at a single location.

Indications for Use :
CT perfusion 2 is an image analysis software package that allows the user to produce dynamic image data and to generate information with regard to changes in image intensity over time. It supports the

analysis of CT Perfusion images obtained by cine imaging after the intravenous injection of contrast in calculation of the various perfusion related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability). The results are displayed in a user-friendly graphic format as parametric images. This software runs on the Advantage Workstation (AW) platform and will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be, for example, related to stroke or tumor angiogenesis and the treatment thereof.

Comparison with Predicate:
CT Perfusion 2 supports the analysis of perfusion CT images and the display of the data in user-friendly graphs and as parametric images. CT Perfusion 2 images as compared with the CT Perfusion device are obtained by CT scanning after an injection of contrast media. CT Perfusion 2 is a software post-processing device and as such does not affect the dosage characteristics or the imaging performance of GEMS CT scanners. The algorithms used to calculate the perfusion parameters are similar to CT Perfusion device. The functional features of this package are substantially equivalent to that of the following device:

Device Name	FDA Clearance Number
CT Perfusion	K993791

Adverse Effects on Health :
The potential hazards are identified in a risk management summary (hazard analysis) and are controlled by:

- Software Development, Validation and Verification Process to ensure performance to specifications, Federal Regulations and user requirements.
- Adherence to industry and international standards.

Conclusions:
The Perfusion 2 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the Perfusion 2 to be equivalent to those of CT Perfusion (K993791).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2001

General Electric Medical Systems
c/o Mr. Reiner Krumme
TUV Rheinland of North America, Inc.
12 Commerce Road
NEWTON CT 06470

Re: K010042
CT Perfusion 2
Dated: December 6, 2000
Received: December 5, 2000
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INTENDED USE

510(k) Number (if known): K010042

Device name: CT Perfusion 2.0

Indication For Use:

CT perfusion 2 is an image analysis software package that allows the user to produce dynamic image data and to generate information with regard to changes in image intensity over time. It supports the analysis of CT Perfusion images obtained by cine imaging after the intravenous injection of contrast in calculation of the various perfusion related parameters (i.e. regional blood flow, regional blood volume, mean transit time and capillary permeability). The results are displayed in a user-friendly graphic format as parametric images. This software runs on the Advantage Workstation (AW) platform and will aid in the assessment of the extent and type of perfusion, blood volume and capillary permeability changes, which may be, for example, related to stroke or tumor angiogenesis and the treatment thereof.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use ______
(Per 21 CFR 801.109)

[signature]
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010042